



FOR US POSTAL SERVICE DELIVERY:

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January 23, 2001

Michael Gottesman, M.D.
Deputy Director for Intramural Research
Building 1, Room 114
9000 Rockville Pike
National Institutes of Health
Bethesda, MD 20892

**RE: Human Research Subject Protections Under Multiple Project Assurance (MPA)
M-1000**

**Research Project: Allelic Variation in Schizophrenia
Project number: 96-M-0110
Principal Investigator: Anil K. Malhotra, M.D.**

**Research Project: Study of CNS Parameters in Normal Controls to be Compared
with Age-Matched Schizophrenic, Depressed, and Personality Disordered Patient
Populations
Project number: 83-M-0114
Principal Investigator: David Pickar, M.D.**

**Research Project: The Behavioral, Neuroendocrine and Neuropsychological Effects
of Ketamine in Schizophrenic Patients and Healthy Volunteers
Project number: 93-M-0175
Principal Investigator: David Pickar, M.D.**

**Research Project: I-123 (RR, RS, SS or SR) 3-Quinuclidynl 4-Iodobenzilate (I-123
QNB) Distribution and Function in Neuropsychiatric Patients and Normal
Volunteers
Project number: 90-M-0007
Principal Investigator: Daniel R. Weinberger, M.D.**

Research Project: and I-123 IBZM SPECT Studies of D2 Receptor Distribution and Function in Neuropsychiatric Patients and Normal Volunteers
Project number: 92-M-0024
Principal Investigator: Daniel Weinberger, M.D.

Dear Dr. Gottesman:

The Office for Human Research Protections (OHRP) has reviewed your January 12, 2001 report regarding the above referenced research projects that was submitted in response to OHRP's December 12, 2000 letter.

Based upon its review of your report, OHRP makes the following determinations:

(1) With respect to the issues related to the initial complaint from the parents of C.P., OHRP acknowledges that the National Institute of Mental Health (NIMH) Institutional Review Board (IRB) has developed a clinically appropriate plan for contacting subjects who were involved in certain research that was conducted without IRB review or the legally effective informed consent of the subjects and informing them of these events. OHRP has determined that this corrective action adequately addresses finding (1) in OHRP's December 12, 2000 letter and is appropriate under the National Institutes of Health (NIH) MPA.

OHRP requests that at your earliest convenience you provide for OHRP's files a copy of the final individualized letters sent to each subject (redacted of subject identifiers) reiterating the details of the disclosure provided to the subject and offering an opportunity for further discussion if desired.

(2) With respect to project number 93-M-0175, OHRP acknowledges that NIMH has implemented a plan to remind its investigators that continuing review reports need to include updates about any recent relevant literature and that informed consent documents need to be updated in a parallel fashion. OHRP has determined that this corrective action adequately addresses finding (3) in OHRP's December 12, 2000 letter and is appropriate under the NIH MPA.

(3) OHRP finds that your January 12, 2001 report adequately responds to each of the outstanding issues and concerns cited in OHRP's December 12, 2000 letter.

As a result, OHRP is closing its compliance oversight investigation of this matter and anticipates no further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Kristina C. Borrer, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Ruth Kirschstein, Acting Director, NIH
Dr. Alan Sandler, Director, OHSR, NIH
Dr. Steven E. Hyman, Director, NIMH
Dr. Donald Rosenstein Chair, IRB, NIMH
Dr. Daniel R. Weinberger, NIMH
Commissioner, FDA
Dr. David Lepad, FDA
Dr. James F. McCormack, FDA
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael A. Carome, OHRP
Dr. Katherine Duncan, OHRP
Mr. George Gasparis, OHRP
Dr. Jeffrey M. Cohen, OHRP
Mr. Barry Bowman, OHRP